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BRYAN CAVE LLP 211 NORTH BROADWAY SUITE 3600 ST. LOUIS, MO 63102-2750			EXAMINER REYES, REGINALD R	
			ART UNIT 3626	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/674,582	<b>Applicant(s)</b> WILSON ET AL.	
	<b>Examiner</b> REGINALD REYES	<b>Art Unit</b> 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1-2-2004</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-25 have been examined.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1-25 are rejected under 35 U.S.C. 101 based on Supreme Court precedent and recent Federal Circuit decisions. Specifically claims 1, 6, 14, 20, 21, 24 and 25 teaches a method dispensing generic pharmaceutical products. It is not tied to a machine or an apparatus. The Office's guidance to examiners is that a § 101 process must (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); and *Cochrane v. Deener*, 94 U.S. 780,787-88 (1876).

Therefore claims 2-5, 7-13, 15-19, and 22-23 are also rejected since they are dependent on the independent claims above.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6-9, 11-13 and 24 are rejected under 35 U.S.C. 102 (b) as being anticipated by Wallace et al (U.S. 6,564,121).

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With respect to claim 1, Wallace teaches a method of dispensing generic pharmaceutical products, wherein the method comprises the steps of: (i) a centralized sourcing agent and distributor receiving one or more generic pharmaceutical products from a plurality of sources (see for example Wallace column 2 lines 37-67); (ii) said centralized sourcing agent and distributor compiling information provided by a plurality of prescribing physicians (see for example Wallace column 28 lines 61-67); (iii) said centralized sourcing agent and distributor identifying physicians who are interested in receiving said generic pharmaceutical products for redistribution to patients (see for example Wallace column 38 lines 6-18 and Fig. 29); and (iv) said centralized sourcing agent and distributor dispensing a plurality of said generic pharmaceutical products to the physicians identified in step (iii) (see for example Wallace column 38 lines 42-53 and column 39 1-12, Fig. 31 and Fig. 33).

4. With respect to claim 2, Wallace teaches the method of dispensing generic pharmaceutical products according to claim 1 (as described above). Wallace teaches wherein at least one of said plurality of sources transfers generic pharmaceutical products to the centralized sourcing agent and distributor by way of donation (see for example Wallace column 2 lines 54-56).

5. With respect to claim 3, Wallace teaches the method of dispensing generic pharmaceutical products according to claim 1 (as described above). Wallace teaches wherein at least one of said plurality of sources transfers generic pharmaceutical

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products to the centralized sourcing agent and distributor by way of sale (see for example Wallace column 10 lines 55-58).

6. With respect to claim 4, Wallace teaches the method of dispensing generic pharmaceutical products according to claim 1 (as described above). Wallace teaches wherein said generic pharmaceutical products include short-dated products (see for example Wallace column 27 lines 49-57).

7. With respect to claim 6, Wallace teaches a method of dispensing generic pharmaceutical products to qualified patients, wherein the method comprises the steps of: (i) a centralized sourcing agent and distributor receiving one or more generic pharmaceutical products from a plurality of sources (see for example Wallace column 2 lines 37-67); (ii) said centralized sourcing agent and distributor compiling information provided by a plurality of patients (see for example Wallace column 1 lines 43-50, column 2 lines 61-67; (iii) from said information and using substantially universal criteria, said centralized sourcing agent and distributor identifying patients who are qualified to purchase said generic pharmaceutical products at reduced prices (see for example column 6 lines 64-67) ; and (iv) said centralized sourcing agent and distributor dispensing a plurality of said generic pharmaceutical products to qualified patients (see for example Wallace column 28 lines 15-21, column 38 lines 42-53 and column 39 1-12, Fig. 31 and Fig. 33).

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8. With respect to claim 7, Wallace teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 6 (as described above). Wallace teaches wherein at least one of said plurality of sources transfers generic pharmaceutical products to the centralized sourcing agent and distributor by way of donation (see for example Wallace column 2 lines 54-56).

9. With respect to claim 8, Wallace teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 6 (as described above). Wallace teaches wherein at least one of said plurality of sources transfers generic pharmaceutical products to the centralized sourcing agent and distributor by way of sale (see for example Wallace column 10 lines 55-58).

10. With respect to claim 9, Wallace teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 6 (as described above). Wallace teaches wherein said generic pharmaceutical products include short-dated products (see for example Wallace column 27 lines 49-57).

11. With respect to claim 11, Wallace teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 6 (as described above). Wallace teaches wherein the centralized sourcing agent and distributor dispenses said generic pharmaceutical products directly to the preferred shipping address of each

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qualified patient (see for example Wallace column 23 lines 46-52).

12. With respect to claim 12 Wallace teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 6 (as described above). Wallace teaches wherein the centralized sourcing agent and distributor dispenses said generic pharmaceutical products to prescribing physicians, wherein said physicians further dispense said generic pharmaceutical products to the appropriate qualifying patients (see fore example Wallace column 38 lines 42-53 and column 39 1-12, Fig. 31 and Fig. 33).

13. With respect to claim 13, Wallace teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 12 (as described above). Wallace teaches wherein the centralized sourcing agent and distributor also compiles information provided by said prescribing physicians. With respect to the type of information provided, it is non-functional descriptive material that does not further limit the step of compiling information. In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01. Furthermore Wallace teaches information comprising each physician's name, patients name, RX#, account number, etc. (see for example Wallace column 12 lines 2-7).



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14. With respect to claim 24 Wallace teaches a method of dispensing generic pharmaceutical products, wherein the method comprises the steps of: (i) a centralized sourcing agent and distributor receiving one or more generic pharmaceutical products from a plurality of sources (see for example Wallace column 2 lines 37-67); (ii) said centralized sourcing agent and distributor compiling information provided by a plurality of patients and physicians (see for example Wallace column 28 lines 61-67 and column 1 lines 43-50, column 2 lines 61-67); (iii) said centralized sourcing agent and distributor identifying pharmacies that are interested in receiving said generic pharmaceutical products for redistribution to patients (see for example Wallace column 2 lines 9-14); and (iv) said centralized sourcing agent and distributor dispensing a plurality of said generic pharmaceutical products to the pharmacies identified in step (iii) (see for example Wallace column 38 lines 42-53 and column 39 1-12, Fig. 31 and Fig. 33).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claims 5 and 10 rejected under 35 U.S.C. 103 (a) as being unpatentable over Wallace et al (U.S. 6,564,121) in view of Rheinhardt et al (U.S. 6,328,700).

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16. With respect to claim 5, Wallace teaches the method of dispensing generic pharmaceutical products according to claim 1(as described above). Wallace does not teach wherein said generic pharmaceutical products include returned products.

Rheinhardt teaches wherein said generic pharmaceutical products include returned products (see for example Rheinhardt column 28 lines 20-25). Therefore it would have been obvious for one of ordinary skill in the art at the time of invention to have generic pharmaceutical products include returned products to make use of all samples and not let it go to waste.

17. With respect to claim 10, Wallace teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 6 (as described above). Wallace does not teach wherein said generic pharmaceutical products include returned products. Rheinhardt teaches wherein said generic pharmaceutical products include returned products (see for example Rheinhardt column 28 lines 20-25). Therefore it would have been obvious for one of ordinary skill in the art at the time of invention to have generic pharmaceutical products include returned products to make use of all samples and not let it go to waste.

18. Claims 14, 15, 17, 18, 19, 20, 21, 22 and 25 rejected under 35 U.S.C. 103 (a) as being unpatentable over Wallace et al (U.S. 6,564,121) in view of Canney (U.S. 6,581,041).

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19. With respect to claim 14, Wallace teaches a method of dispensing generic pharmaceutical products to qualified patients, wherein the method comprises the steps of: (iii) said centralized sourcing agent and distributor compiling information provided by a plurality of patients (see for example Wallace column 38 lines 6-18 and Fig. 29); (iv) from said information and using substantially universal criteria, said centralized sourcing agent and distributor identifying patients who are qualified to purchase said generic pharmaceutical products at reduced prices (see fore example Wallace column 38 lines 42-53 and column 39 1-12, Fig. 31 and Fig. 33); and (v) said centralized sourcing agent and distributor dispensing said generic pharmaceutical products to qualified patients (see fore example Wallace column 28 lines 15-21, column 38 lines 42-53 and column 39 1-12, Fig. 31 and Fig. 33). Wallace does not teach: (i) one or more charitable foundations receiving one or more generic pharmaceutical products from a plurality of sources; (ii) said one or more charitable foundations transferring said generic pharmaceutical products to a centralized sourcing agent and distributor. Canney teaches a donor to a charitable community foundation (see for example Canney column 2 lines 20-23). It would have been obvious to one of ordinary skill in the art at the time of invention to have charitable foundation receiving generic pharmaceutical products from a plurality of sources to accumulate more donated items.

20. With respect to claim 15, Wallace in view of Canney teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 14

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(as described above). Wallace teaches wherein said generic pharmaceutical products include short-dated products (see for example Wallace column 27 lines 49-57).

21. With respect to claim 17 Wallace in view of Canney teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 14 (as described above). Wallace teaches wherein the centralized sourcing agent and distributor dispenses said generic pharmaceutical products directly to the preferred shipping address of each qualified patient (see for example Wallace column 23 lines 46-52).

22. With respect to claim 18, Wallace in view of Canney teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 14 (as described above). Wallace teaches wherein the centralized sourcing agent and distributor dispenses said generic pharmaceutical products to prescribing physicians, wherein said physicians further dispense said generic pharmaceutical products to the appropriate qualifying patients (see fore example Wallace column 28 lines 15-21, column 38 lines 42-53 and column 39 1-12, Fig. 31 and Fig. 33).

23. With respect to claim 19, Wallace in view of Canney teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 18 (as described above). Wallace teaches wherein the centralized sourcing agent and distributor also compiles information provided by said prescribing physicians. With

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respect to the type of information provided, it is non-functional descriptive material that does not further limit the step of compiling information. In re Gulack, 217 USPQ 401 (Fed. Cir. 1983), In re Ngai, 70 USPQ2d (Fed. Cir. 2004), In re Lowry, 32 USPQ2d 1031 (Fed. Cir. 1994); MPEP 2106.01. Furthermore Wallace teaches information comprising each physician's name, patients name, RX#, account number, etc. (see for example Wallace column 12 lines 2-7).

24. With respect to claim 20 Wallace teaches A method of dispensing generic pharmaceutical products, wherein the method comprises the steps of: (i) a centralized sourcing agent and distributor receiving one or more generic pharmaceutical products from a plurality of sources (see for example Wallace column 2 lines 37-67); (ii) said centralized sourcing agent and distributor compiling information provided by a plurality of prescribing physicians (see for example Wallace column 28 lines 61-67), column 2 lines 61-67; (iii) said centralized sourcing agent and distributor identifying physicians who are interested in receiving said generic pharmaceutical products for redistribution to patients (see for example column 6 lines 64-67). Wallace does not teach (iv) said centralized sourcing agent and distributor transferring a plurality of said generic pharmaceutical products to one or more charitable foundations; and (v) said one or more charitable foundations dispensing said generic pharmaceutical products to the physicians identified in step (iii). Canney teaches a donor to a charitable community foundation (see for example Canney column 2 lines 20-23). It would have been obvious to one of ordinary skill in the art at the time of invention to have the a

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centralized sourcing agent and distributor transferring a plurality of said generic pharmaceutical products to one or more charitable foundations and said one or more charitable foundations dispensing said generic pharmaceutical products to the physicians to get more donated items and dispose of them more efficiently.

25. With respect to claim 21, Wallace teaches a method of dispensing generic pharmaceutical products to qualified patients, wherein the method comprises the steps of: (i) a centralized sourcing agent and distributor receiving one or more generic pharmaceutical products from a plurality of sources(see for example Wallace column 2 lines 37-67); (ii) said centralized sourcing agent and distributor compiling information provided by a plurality of patients(see for example Wallace column 1 lines 43-50, column 2 lines 61-67 ; (iii) from said information and using substantially universal criteria, said centralized sourcing agent and distributor identifying patients who are qualified to purchase said generic pharmaceutical products at reduced prices (see for example column 6 lines 64-67). Wallace does not teach (iv) said centralized sourcing agent and distributor transferring a plurality of said generic pharmaceutical products to one or more charitable foundations; and (v) said one or more charitable foundations dispensing said generic pharmaceutical products to qualified patients. Canney teaches a donor to a charitable community foundation (see for example Canney column 2 lines 20-23). It would have been obvious to one of ordinary skill in the art at the time of invention to have the a centralized sourcing agent and distributor transferring a plurality of said generic pharmaceutical products to one or more charitable foundations and said

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one or more charitable foundations dispensing said generic pharmaceutical products to the physicians to get more donated items and dispose of them more efficiently.

26. With respect to claim 22, Wallace in view of Canney teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 21 (as described above). Wallace in view of Carrey teaches wherein the one or more charitable foundations dispense said generic pharmaceutical products directly to the preferred shipping address of each qualified patient (see for example Wallace column 23 lines 46-52).

27. With respect to claim 23, Wallace in view of Canney teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 21 (as described above). Wallace in view of Carrey teaches wherein the one or more charitable foundations dispense said generic pharmaceutical products to prescribing physicians, wherein said physicians further dispense said generic pharmaceutical products to the appropriate qualifying patients (see for example Wallace column 38 lines 42-53 and column 39 1-12, Fig. 31 and Fig. 33).

28. With respect to claim 25 Wallace teaches a method of dispensing generic pharmaceutical products, wherein the method comprises the steps of: (i) a centralized sourcing agent and distributor receiving one or more generic pharmaceutical products from a plurality of sources (see for example Wallace column 2 lines 37-67); (ii) said

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centralized sourcing agent and distributor compiling information provided by a plurality of patients and physicians (see for example Wallace column 28 lines 61-67 and column 1 lines 43-50, column 2 lines 61-67); (iii) said centralized sourcing agent and distributor identifying pharmacies that are interested in receiving said generic pharmaceutical products for redistribution to patients (see for example Wallace column 2 lines 9-14); and (iv) said centralized sourcing agent and distributor dispensing a plurality of said generic pharmaceutical products to the pharmacies identified in step (iii) (see for example Wallace column 38 lines 42-53 and column 39 1-12, Fig. 31 and Fig. 33).

Wallace does not teach (i) a centralized sourcing agent and distributor receiving one or more generic pharmaceutical products from one or more charitable foundations.

Canney teaches a donor to a charitable community foundation (see for example Canney column 2 lines 20-23). It would have been obvious to one of ordinary skill in the art at the time of invention to have charitable foundation receiving generic pharmaceutical products from a plurality of sources to accumulate more donated items.

29. Claim 16 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Wallace et al (U.S. 6,564,121) in view of Canney (U.S. 6,581,041) in view of Rheinhardt et al (U.S. 6,328,700).

30. With respect to claim 16 Wallace in view of Canney teaches the method of dispensing generic pharmaceutical products to qualified patients according to claim 14 (as described above). Wallace in view of Canney does not teach wherein said generic pharmaceutical products include returned products. Rheinhardt teaches wherein said



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generic pharmaceutical products include returned products (see for example Rheinhardt column 28 lines 20-25). Therefore it would have been obvious for one of ordinary skill in the art at the time of invention to have generic pharmaceutical products include returned products to make use of all samples and not let it go to waste.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,803,498 teaches pharmaceutical marketing device and system.

U.S. Patent No. 6,253,998 teaches fund-raising terminal and method for accepting monetary contributions by use of an information bearing card.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REGINALD REYES whose telephone number is (571)270-5212. The examiner can normally be reached on 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on 571-272-6670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. R./

Examiner, Art Unit 3626

/C Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626